



Sanofi pasteur finds the cure for compliance management.

The Challenge

Sanofi pasteur needed an Internet-based solution for tracking a wide variety of requirements, including very stringent FDA regulations. The EHS staff wanted to save time and improve data quality simultaneously.

The Solution

Only the Enviance System offered an Internet platform that could automate tasking and calculations for their entire compliance program, maximizing their investment.

The Benefits

- System flexibility
- IT simplicity
- Time savings
- Institutional knowledge
- Accountability

As the vaccines division of one of the world's largest pharmaceutical companies, sanofi pasteur has compliance requirements that span a variety of regulatory agencies and cover everything from air, water, and waste to vaccine sampling by the Food and Drug Administration (FDA). When the organization began its search for a compliance management system, they were looking for a solution to ease the burden on the compliance staff, without requiring additional support from the Information Solutions (IS) department.

Sanofi pasteur selected the Enviance System based on its Internet platform, and ability to handle tasks, calculations, and reporting for multiple regulatory agencies. Data only needs to be entered once, and is manipulated to fit all of the organization's requirements:

- Title V
- Discharge Monitoring Report (DMR)
- Infectious and hazardous waste tracking
- FDA's current Good Manufacturing Practice (cGMP)
- Sustainability and annual shareholder reporting
- Green reporting in Canada



A long history in vaccine production, with a bright future for compliance management.

Sanofi pasteur is the largest company in the world devoted entirely to human vaccines, and the Swiftwater, PA laboratory has been producing vaccines for more than 100 years. With a rich history in the medical field and countless compliance regulations, the organization needed a comprehensive and reliable solution to satisfy all of their compliance requirements.

System flexibility allows for maximum usage – and maximum value.

Because the organization had limited personnel resources in the environmental, health and safety (EHS) department, sanofi pasteur began looking at compliance management systems to streamline processes, improve data quality, and save time. The Enviance System was initially used to automate fuel permit calculations on an hourly basis.

Enviance has allowed the organization to automate these calculations and provides a host of other applications:

- ▶ Compliance calendar to ensure tasks are completed
- ▶ Easy manipulation of data – enter once for multiple requirements and eliminate redundancy
- ▶ Integration with an onsite data system – Prodigy Historian
- ▶ Data management across the board – air, water, waste, and recycling

Multiple layers of security protect compliance data.

Security was a concern for sanofi pasteur, because they wanted to manage a large amount of compliance data with an Internet-based solution. The Enviance System is safeguarded by multiple layers of security, and data backups are done every day.

The internal IS team performed an audit of Enviance's protocols and procedures before deciding that it was the right solution. The Enviance System met their security criteria, and even made their jobs easier because all data is now securely hosted by Enviance and stored offsite.

Waste tracking: from generation to destruction.

New and innovative strategies are being used to make infectious and hazardous waste tracking easier and more precise. Sanofi pasteur is using Personal Data Assistants (PDAs) to scan barcodes on waste containers. They are tracked from the research bench, to the truck, to the incinerator. This has automated the tracking process and as opposed to spreadsheets and checklists, has greatly improved the accuracy of data.

Institutional knowledge has allowed sanofi pasteur to improve performance.

The Enviance System allows the organization to document their processes and detail their requirements. This kind of institutional knowledge provides assurances that best practice standards are being followed as personnel easily and confidently complete tasks. Sanofi pasteur quickly resolves issues that might otherwise go unnoticed.

Rather than implement a variety of systems to manage compliance requirements, sanofi pasteur selected the Enviance System as their compliance solution of choice – thereby maximizing value and improving the quality of their data.

Learn more at:
www.enviance.com
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